Biotechnology Regulatory Services
STAKEHOLDER NEWSLETTER

Message from the Deputy Administrator

Hello! Another eventful year is coming to an end at APHIS' Biotechnology Regulatory Services (BRS). We achieved a number of significant accomplishments this year and we will continue to move forward on key initiatives in 2009.

In June of this year we received the International Organization for Standardization certification for our notification and permitting processes. In September, we published a request for information on genetically engineered animals (GE) that will inform future policy direction in this area. Additionally, in October, we published proposed revisions to APHIS regulations in 7CFR part 340 that govern the import, interstate movement, and environmental release of certain GE organisms. We also launched a Biotechnology Quality Management System pilot project and implemented enhancements to our ePermits system. Work will continue on all these initiatives in 2009.

We also made significant progress in the international arena this year, working in coordination with Canada, Mexico, China, and India on some key initiatives. These interactions are part of a larger initiative to assist APHIS in building critical relationships with international countries to encourage science-based biotechnology regulation programs worldwide.

I invite you to read more about the current status of this year's initiatives and learn about some additional 2008 accomplishments in this newsletter. We hope you find this stakeholder update informative, and encourage you to visit our Web site (http://www.aphis.usda.gov/biotechnology) for our latest news and information.

If you have not already done so, we also invite you to register with our on-line BRS stakeholder registry to ensure that you receive all future stakeholder updates at: https://web01.aphis.usda.gov/BRS/BRSWeb.nsf.

Sincerely,
Michael Gregoire
BRS Deputy Administrator

BRS Enhances its ePermits System

In the fall of 2008, BRS launched a new biotechnology inspection component of its ePermits System. The ePermits System allows the electronic processing and tracking of permit applications. Individuals are able to process permit applications on-line for Biotechnology Regulatory Services' notifications and permits, as well other Agency permits. Submitting applications and receiving permits via the internet saves customers time and effort. It also enables APHIS regulatory officials to issue and track permits, thus reducing delivery time and expenses. The new component allows BRS to initiate, process, and track compliance inspections for the field testing of regulated genetically engineered organisms. With these enhancements, APHIS can quickly search inspection history, allowing the agency to more easily identify, track, and resolve potential problem areas and compliance incidents. Enhancements to the system include the capacity to combine inspection data with real-time weather data to monitor compliance conditions when severe weather occurs and an automated system for tracking and reporting inspections and compliance activities.

APHIS Launches Biotechnology Quality Management System Pilot Project

In fall 2008, BRS launched the pilot project for its Biotechnology Quality Management System (BQMS) program. BQMS is a voluntary compliance assistance program to help biotechnology researchers and companies to develop plans and practices to facilitate compliance with biotechnology regulatory requirements. This system will help universities, small businesses, and large companies develop sound management practices, and enhance compliance with regulatory requirements for field trials and movements of genetically engineered organisms by providing a mechanism to analyze their operations, identify control points where problems could occur, and apply mitigation measures to address vulnerabilities to regulatory compliance.

The goal of the pilot project is to test and obtain feedback from participants on the strengths and areas for improvement to the BQMS audit standard and guidelines prior to full implementation of the system. BRS published a notice in the Federal Register soliciting letters of interest from the regulated community to participate in the pilot project. Five organizations including an academic institution, one small company, and three large companies were selected for the pilot project. The pilot project will begin with training sessions for the participants in January 2009.

APHIS Gathers Comments on Proposed Changes to Biotechnology Regulations

In October 2008, APHIS published a proposed rule regarding its biotechnology regulations (Code of Federal Regulations, Volume 7, Section 340) in the Federal Register. The proposed rule was available for public comment through November 24, 2008. The proposed rule outlines revisions to existing biotechnology regulations regarding the introduction (importation, interstate movement, and environmental release) of certain genetically engineered (GE) organisms, including plants, GE arthropods (e.g. insects) and other invertebrates. To facilitate public participation in the rulemaking process, APHIS held three public forums in October and

November 2008. These forums were held in Davis, California; Kansas City, Missouri; and Riverdale, Maryland. The format consisted of informational posters and comment stations where attendees were able to interact with APHIS personnel and provide comments.

While BRS' current regulations have been effective in ensuring the safe introduction of GE organisms, the program is considering potential revisions to update its existing regulations in light of advances in science and technology and to reflect APHIS' experience overseeing the introduction of GE organisms by incorporating its lessons learned. Revising our biotechnology regulations will better position us to address new challenges, as well as meet current needs in evaluating and addressing potential plant pest or noxious weed risks associated with the introduction of certain GE organisms. The proposed changes will also improve regulatory processes so they are more transparent to stakeholders and the public, make more efficient use of agency resources, and eliminate unnecessary regulatory burdens. Changes that APHIS is considering include: aligning the regulations with the plant pest and noxious weed provisions of the Plant Protection Act, discontinuing the notification procedure, adapting the permitting system to address a wide variety of different species and genetic modifications, improving and clarifying the petition procedure to approve non-regulated status, and establishing a new petition procedure for APHIS to approve new conditional exemptions from the requirement to obtain a permit. APHIS received over 15,000 comments that it will review and consider before going forward with next steps in the rulemaking process.

APHIS Gathers Information on Genetically Engineered Animals

In September 2008, APHIS published a Request for Information (RFI) on Genetically Engineered (GE) Animals to gather information from the public before drafting official guidance or policy. The Agency was seeking information to determine current research that is being conducted with GE animals; identify the implications of the importation and interstate transportation of GE animals on the health of the U.S. livestock population; and coordinate any GE animal policy with the Food and Drug Administration (FDA) policies. Currently, most GE animals are being developed to support human and veterinary medicine. These animals are being engineered to study and address issues such as diabetes, blood clotting, and possible resistance to diseases such as Bovine Spongiform Encephalopathy (BSE) – otherwise known as mad cow disease. APHIS is in the process of reviewing the comments.

APHIS Works with International Partners to Strengthen Biotechnology Regulation Worldwide

In 2008, APHIS made some significant progress in the international arena, working in coordination with Canada, Mexico, China, and India on key initiatives. These interactions are part of a larger initiative to assist APHIS in building critical relationships with international countries to encourage science-based biotechnology regulation programs. We participated in multiple trilateral activities with Mexico and Canada to exchange information and harmonize approaches to biotechnology regulation and are pleased to have played a role in Mexico's adoption of new regulations for oversight of agricultural biotechnology in March 2008. We also

participated in a workshop in October 2008 to provide Mexico with expertise and experience in conducting field trials as they consider allowing genetically engineered (GE) maize to be planted for the first time in 10 years. We will continue to work with Mexico to provide them with information as they move forward with this initiative. Additionally, APHIS worked with China this year as part of a biotechnology technical working group to exchange information and identify common approaches for regulation and communication regarding GE plants. We also continued to participate in ongoing training activities with India to share information on the science-based risk assessment processes the Agency uses for regulating GE organisms.

Planning for the 2009 Permit Season

The 2009 growing season is fast-approaching. We recommend that applicants submit their 2009 permits and/or notifications promptly. Early submission allows BRS to optimally plan resources to efficiently review applications and complete necessary documents, including environmental assessments, in time to meet planting requests. We encourage applicants to ensure that their application is complete to avoid delays in review and approval. APHIS can not assure timely approval of permits received less than 120 days before planting. Also, please keep in mind, applications that involve preparation of an environmental assessment will require additional time beyond the 120 days.

As BRS develops its business plan for 2009, we will look at ways to increase our efficiency and maximize the resources we devote to our core functions, including the processing of notifications, permits, and petitions. We encourage our regulated community to take the time to meet with us to inform us of their long term plans so that we can better prepare for future requests. As we move forward in our planning, we will continue to communicate with you about this important issue. If you have questions about the permit/notification process, please send an e-mail to biotechquery@aphis.usda.gov.

BRS Employee Spotlight

In each quarterly stakeholder update, BRS will highlight one of our employees so that our stakeholders can see the variety of work done in our program.

Employee: Cynthia A. Eck
Position:
Document Control Officer, Biotechnology Regulatory Services, Regulatory Operations, Document Management Branch
Time with BRS:
2 years, 1 month—I joined BRS in November 2006 and have been working on streamlining our document control work processes. In my first year I became certified as a Quality Management System Auditor/Lead Auditor/Senior Auditor. This lead to a team effort with the Document Management Branch receiving certification for our efforts to operate a Quality Management System which complies with the requirements of ISO 9000 - 2001.

Activities prior to joining BRS:
I worked for APHIS Legislative and Public Affairs for 14 years first as a Public Affairs Specialist and then as a Freedom of Information Act Program Specialist—assigned to communication and administrative lawsuit responsibilities for BRS and the former Biotechnology, Biologics and Environmental Protection program. During my tenure, I was also detailed in 2001 to the Acting Branch Chief position with APHIS' Forms, Issuances and Records Management Staff. It was during this time that I became certified in Records Management administration with the National Archives and Records Administration.

Education:
I have a B.A. degree in English and Journalism from the University of Delaware.

Job Description:
I am responsible for coordinating and ensuring conformity in all document controls, policies and procedures. I provide consultation and guidance on document control issues and assist with the ongoing development of technical information, policies and procedures. I support and maintain a quality management system (ISO).

Proudest Accomplishment:
Most recently, I completed APHIS' BRS Leadership Development Program. This 12 month course provided me the opportunity not only to learn more about BRS and APHIS' culture, but also to learn more about myself. I was professionally challenged by taking on a shadowing assignment with APHIS' Policy and Program Development staff. As a result, I have become more savvy to needs of our stakeholders.

What motivates you about your job:
Being a public servant is an awesome responsibility. As the daughter of a WWII vet, I feel very proud to give back to the American public clear, honest and concise communication concerning the work of the federal government. Harnessing the powers of new technology to keep the American public more informed about our regulatory work is not only my responsibility but my motivation. Ensuring that our information is maintained and controlled to provide a concise picture of our work and those we regulate is my goal. I truly enjoy encouraging and soliciting communication between my colleagues and our stakeholders to create an environment that challenges us toward excellence in our work.

Administrative Update

BRS' Office of the Deputy Administrator is pleased to have a new Chief of Staff. Clint Nesbitt began in this position in December after serving as BRS' Communication and Outreach Program Specialist on BRS' Policy Coordination Programs for over 3 years. In his new role, Clint will serve as a liaison of communication between staff, management, administration, and stakeholders. He will also coordinate, manage, and track progress of daily activities and issues of headquarters operations.

The Regulatory Operations Program has four new staff members serving in the Compliance and Inspection Branch to help applicants maintain compliance with APHIS regulations. Catharine

Cook is our new Regional Biotechnologist in the Eastern Regional office, located in Raleigh, NC. Catherine's expertise in the biological sciences is a welcomed addition to the inspection team as we are constantly challenged with oversight of a wide array of plant, animal and microbial species. Salee Norton is our new Program Support Assistant in the Eastern Regional office, providing critical administrative support to our Eastern Regional staff. Carl Ettsity has joined us as our new Regional Biotechnologist in our Western Regional office in Ft. Collins, CO. Carl comes to us from the U.S. Environmental Protection Service with a background in environmental science. We also have a new staff member at APHIS headquarters—Eddie Serrano is serving as our new Regulatory Specialist. Eddie comes to us after serving as an inspector for APHIS' Plant Protection and Quarantine.

We also have two new Biotechnologists in our Environmental and Risk Analysis Program who will serve to evaluate notifications, permits, and petitions. Jordan Sottosanto joins us from the Department of Homeland Security and brings us expertise in plant molecular biology. Shailaja Rabindran brings us over 15 years experience in Plant Biotechnology and Plant Pathology.

Kelli Brisco, Office of the Deputy Administrator and Alonza Gibbs, Environmental Risk Analysis Programs, two valued members of our administrative staff, moved on to new positions in APHIS. Deborah Wier is a new member of our administrative staff who is currently serving both BRS program areas as a result of these losses.

If you need to contact any of our new staff members, please call 301-734-7324.

Interested in Working in BRS?

If you or someone you know is interested in working for BRS, you can view and apply for current job vacancies by visiting http://jobsearch.usajobs.opm.gov/ and searching for "Biotechnology Regulatory Services" (in quotes).

Have questions about BRS policy and regulations? E-mail us at biotechquery@aphis.usda.gov

Fiscal Year 2008 Total Submissions

Notifications Acknowledged
250 Importation
378 Interstate Movement
216 Environmental Release
617 Combined Interstate Movement/Release

Permits Issued
49 Importation
75 Interstate Movement
50 Environmental Release
31 Combined Interstate Movement/Release
674 Courtesy Permits

Petitions/Extensions for Non-Regulated Status
0 Petitions Received